

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,304	11/08/2001	Timothy Ringeisen	KN P-0020	5717

7590 01/30/2003
Jeffrey C. Kelly, Esq.
Kensey Nash Corporation
55 East Uwchlan Avenue
Exton, PA 19341

EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,304	RINGEISEN, TIMOTHY	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Acknowledgement of Papers Received: Amendment and Response filed on 11/13/02.

Response to Arguments

1. Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the dissolution of polyurethane with tetrahydrofuran and a second solvent selected from the group comprising p-dioxane, dimethyl sulfoxide and o-xylene, thereby creating a gel does not reasonably provide enablement for the dissolution of any polymer with any two solvents to create said gel. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.
3. The factors which determine that a disclosure does not satisfy the requirements for enablement are supported by *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The factors which determine enablement are:

- a. Breadth of the claims

Art Unit: 1615

The breadth of the claims as of filing are directed to a method of making a porous gel by dissolving any polymer in any solvent. The solution is then combined with any other solvent to create a gel, which is then shaped into a porous polymeric structure.

b. Nature of the invention

The nature of the invention is that of porous polymeric materials. The making and use of porous polymeric materials for various utilities including drug delivery and/or coating purposes is well known in the art.

c. State of the prior art

It is known in the art how to produce porous polymeric structures, which act as scaffolds for bioactive agents. As seen in Fox, Jr. et al (USPN 5,019,096) which discloses various polymers including polyurethane being dissolved by a solvent, the dissolution of polymers in solvent is well known in the art. A further solvent is used in the processing and a porous scaffold material is formed, after the solvents are removed. The reference however does not disclose the creation of a gel from this two solvent process. Nishijima (USPN 3,619,250) discloses that polyurethane can be dissolved in various solvents including those as claimed by applicant. The state of the prior art establishes that polymers such as polyurethane can be dissolved in solvents such as those recited by applicant, to produce porous scaffolds, which can act as coatings or carriers.

d. The level of one of ordinary skill

The level of one of ordinary skill in the polymer arts is considered a master level and is quite substantial. Yet, even at such a high level of skill, there would be required undue experimentation on the part of the skilled artisan in order to practice the invention.

Art Unit: 1615

e. The level of predictability in the art

As described in item c, the art provides teachings that would predictable produce a porous polymeric material for a specific group of polymers, using a specific class of solvents. Yet as previously stated the disclosure of applicant does not provide sufficient evidence that the process would work for every polymer using every solvent.

f. The amount of direction provided by the inventor

Applicant provides, through the use of examples and the disclosure of the specification sufficient direction for the use of a particular class of polymers, along with a specific class of solvents. Applicant also does not provide ratios or ranges for the working components of the invention.

g. The existence of working examples

Applicant provides working examples of specific polymers including polyurethane being processed with two separate solvents. Applicant does not provide examples, which would apply to any and all polymers being dissolved by any and all solvents.

h. The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

As the claims are presently presented, a skilled artisan would have to experiment with every known polymer and every known solvent in order to achieve porous gel claimed by applicant. There would be undue experimentation on the part of the skilled artisan since not even a class of polymers or solvents is named in the claims.

As a note claims that recite the polymer and the specific solvents such as claims 12 – 14 (with the amendment to claim 13) would be enabled by the disclosure if they recited a particular

Art Unit: 1615

ratio of the polymer to the particular solvents. Again the issue of undue experimentation arises, where the skilled artisan would have too wide a range of variables in order to arrive at the invention of applicant.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

M. Young
January 25, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600